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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,513

12/21/2004

Jeremy Marshall

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8360

466

7590

08/27/2009

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

08/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,513	Applicant(s) MARSHALL, JEREMY	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/10/2009 has been entered.

Double Patenting

2. Applicant is advised that should claim 18 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 12, 14, 18, and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall et al. (US 5,487,748; "Marshall") in view of Morita (US 5,628,765). Marshall discloses a lancet comprising a needle having a pointed tip, a support body (8) enclosing the needle such that the pointed tip (19) projects beyond the end of the support body, and a removable guard (20, 22) located over the pointed tip of the needle, the guard made from

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molded plastics material and connected thereto by a breakable neck portion (21). The removable guard portion has a region of thinner section (22) and a tip encasing region (20) encasing the tip of the needle (fig. 1 shows side view) wherein the tip encasing region is thicker than the thinner section (22). Marshall discloses that various parts of the device are made from molded plastics but fails to expressly disclose that the guard is integrally molded with the support body. However, since the support body and guard are connected by a frangible neck, it would have been obvious to use a single mold to form the connected pieces. Marshall also fails to disclose the claimed peripheral thickened rib.

5. Morita teaches that it is well known to include a u- or c-shape peripheral thickened rib around a central region of thinner section on a removable guard ("98"; fig. 10 and 11). The thickened rib is advantageous because it facilitates gripping of the guard for its removal. It would have been obvious to one skilled in the art to add such an outer peripheral thickened rib as taught by Morita to the device of Marshall so that it too would have this advantage. With this rib, the thinner region (22 inside of thicker rib taught by Morita) can be considered a central region of thinner section than the rib which is partly surrounded by the rib. The tip encasing region is spaced from the adjacent ends of the rib such that there are respective gaps therebetween bridged only by the thinner central section.

6. Regarding claims 18 and 20, the thickened ribs are disposed beside the needle (next to an end side) and are therefore disposed laterally of the needle. The end of the needle can be considered a side of the needle. The ends can be considered laterally adjacent to a side of the needle since they are near a side of the needle.

7. **Claims 13 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Morita as applied to claim 12 above and further in view of Crossman (GB

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2,352,403). Marshall in view of Morita discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point.

8. Crossman discloses that it is well known to have a hole (8) formed in the distal end of a plastic injection-molded guard (figs. 1-3). Adding such a hole to the modified device of Marshall would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Regarding claim 17, the guard is tab-like with a thickened rib as taught by Morita.

9. **Claims 15 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Morita and Higgins (US 3,358,689). Marshall in view of Morita discloses a lancet having the claimed structure and Morita teaches forming the lancet using plastic injection molding process wherein a mold is constructed with cavities arranged to result in the structure of the lancet above (col. 7 ll. 23-29). In order to attain the structure of the lancet of Marshall in view of Morita as discussed in detail above with respect to claim 12, it would have been obvious to construct the mold to have an outer peripheral thickened hollow region of generally u or c shape which leads to a thinner hollow section and a further enlarged hollow region encasing the needle spaced from the ends of the peripheral thickened hollow region to leave a gap therebetween that is bridged only by the thinner hollow section. Morita does not expressly teach an entry point for the plastics material at an end remote from the needle point. However, Higgins discloses that it is well known to provide an entry point (88) in a lancet guard mold at an end of the guard remote from the pointed needle tip and it would have been obvious to provide such an entry point positioned in this manner on the mold of Morita as it provides a way of delivering the plastics material with predictable results. Regarding claim 19, as discussed above, the ends of the rib are disposed laterally the needle.

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10. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Morita and Higgins as applied to claim 15 above, and further in view of Crossman (GB 2,352,403). Marshall in view of Morita and Higgins discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point as well as a pin to cause the plastics material to flow around pin, thereby forming the hole.

11. Crossman discloses that is well known to have a hole (8) formed in the distal end of a guard (figs. 1-3). Adding such a hole to the modified device of Marshall would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Crossman discloses that pins can be used to form holes in an injection molded plastics body (p. 3 ll. 7-9) and it would have been obvious to use such a pin in order to easily form the hole in the guard.

Response to Arguments

12. Applicant's arguments filed 6/10/2009 have been fully considered but they are not persuasive. Applicant argues that it would not have been obvious to add the thickened peripheral rib of Morita to the arrangement of Marshall. As discussed above, a thickened peripheral rib provides an edge that facilitates gripping of the cap for its eventual removal. Although this advantage is not expressly disclosed by Morita, it is the examiner's position that one skilled in the art would recognize that such an advantage flows naturally from the disclosure of the thickened peripheral rib. It is further noted that applicant appears to have recognized this undisclosed advantage (prior to the examiner's assertion) on page 7 of the remarks filed 11/19/2008, where applicant states that Morita discloses "a raised peripheral rib to assist gripping".

13. In response to applicant's argument that the combination of Marshall and Morita would result in applying the entire head of Morita to the stem of Marshall, the test for obviousness is

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not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). One skilled in the art would recognize that the feature of the thickened peripheral rib of Morita finds merit on other tab-like removable caps, including the cap disclosed by Marshall.

14. Regarding new claims 18-20, the ends of the rib taught by Morita can be considered disposed laterally of the needle and laterally adjacent the needle. In particular, laterally disposed has been taken to mean that the rib ends are disposed near or on a side of the needle. The end of the needle is considered a side of the needle and the ends are near this side of the needle and are therefore considered adjacent to this side. That is to say, the entire cap can be considered adjacent to the needle.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 8/20/2009

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/26/09